International Application No.: PCT/JP2003/011462
International Filing Date: September 8, 2003
Assignee: ARKRAY Inc.
Title of the Invention:
TEST KIT AND PROCESS FOR PRODUCING THE SAME

DECLARATION

I, Tatsuya TANAKA, hereby declare:

that I am a translator residing in Osaka Japan;

that I am well acquainted with both the Japanese and English languages;

that, for entering the national phase of the above-identified international application, I have prepared an English translation of the Japanese specification and claims as originally filed with the Japanese Patent Office (Receiving Office); and

that the said English translation corresponds to the said Japanese specification and claims to the best of my knowledge.

I also declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statements is directed.

Declared at Osaka, Japan on February 17, 2005
By Tatsuya TANAKA

T. Tanaka
Signature

5/PRTS

10/526297

DESCRIPTION

BT01 Rec'd PCT/PTC 01 MAR 2005

TEST KIT AND PROCESS FOR PRODUCING THE SAME

TECHNICAL FIELD

This invention relates to a test kit used in the analysis of specific components in a sample liquid, and to a process for producing such a test kit.

BACKGROUND ART

With a dry test kit, as shown in Figs. 7 and 8, a plurality of coloration pads 91 are arranged in a matrix on a carrier 90. All of the coloration pads 91 are covered by a single spreading penetration layer 92. With this dry test kit 9, when the spreading penetration layer 92 is spotted with a sample liquid, the sample liquid spreads out in the planar direction of the spreading penetration layer 92 while penetrating into the spreading penetration layer 92 in the thickness direction. As a result, all of the sample liquid is supplied to the coloration pads 91.

With the dry test kit 9, because the spreading penetration layer 92 allows the sample liquid to spread out in the planar direction after the supply of the sample liquid, liquid junctions may be formed between adjacent coloration pads 91, resulting in interference between these coloration pads 91. In other words, the

coloring substance that seeps out of one coloration pad 91 may be admixed into an adjacent coloration pad 91 via the spreading penetration layer 92.

One possible way to suppress such interference is to ensure plenty of distance between adjacent coloration pads 91. Nevertheless, if the distance between the coloration pads 91 is increased, this makes the dry test kit 9 larger, and more sample liquid is required for testing.

Another possible way to suppress interference, as shown in Figs. 9 and 10, is to provide a partition 93 between adjacent coloration pads 91 (see, for example, Japanese Laid-Open Patent Application 2002-71684), or to provide a water repellant layer between adjacent coloration pads 91 (see, for example, Japanese Laid-Open Patent Application 2001-349835).

However, providing a partition 93 or a water repellency treatment is disadvantageous in terms of both cost and work efficiency in the production of the test kit. Also, the coloration pads 91 need to be formed small in order to keep the test kit to a compact size, but this requires that the width of the partition 93 also be smaller. Accordingly, when the coloration pads 91 are formed in a small size of 1 mm square, for example, a costly apparatus has to be used to form the partition 93, which is disadvantageous in terms of producing cost.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to allow an analytical kit comprising a plurality of coloration pads to be produced at low cost, and to suppress interference between adjacent coloration pads while also keeping the size of the test kit small.

A first aspect of the present invention provides an analytical kit or a test kit which comprises a penetration layer and a plurality of coloration pads in contact with the penetration layer, wherein a sample liquid supplied to the penetration layer is fed to each of the coloration pads through the penetration layer. The penetration layer allows liquid penetration mainly thicknesswise of the penetration layer while restricting the liquid penetration in the planar direction of the penetration layer.

In the test kit of the present invention, the plurality of coloration pads and the penetration layer are laminated in this order on a carrier. The carrier is preferably formed of a non-water-absorbent material. Examples of materials that can be used to form a non-water-absorbent carrier include PET, PC, and like resin materials.

The penetration layer and the plurality of coloration pads may also be laminated in this order on a water absorbent carrier. In this case, the sample liquid supplied to the water absorbent carrier is supplied to

the coloration pads through the penetration layer. The water absorbent carrier can be a porous material, for example. Examples of porous materials that can be used include paper materials, foams, woven fabric materials, nonwoven fabric materials, knit materials, glass filters, and gelled materials.

The penetration layer can be, for example, a penetration membrane which is formed with a plurality of thicknesswise extending pores. The plurality of pores have a size of e.g. 0.1~12μm, and the porosity of the penetration membrane is set to lie in the range of 4~20vol% for example.

The penetration membrane is preferably a track etched membrane formed by track etching. Track etching is a method in which a polymer film is bombarded with neutrons, and pores are formed by chemical etching. With this method, the pore size and porosity can be controlled by varying the neutron bombardment time or the etching treatment time. Naturally, the penetration membrane can also be a glass filter or one having a honeycomb structure.

The plurality of coloration pads are arranged in a matrix, for example, but the plurality of coloration pads can also be arranged in a straight line. The plurality of coloration pads are formed within a specific region, and the surface area of the specific region is 2.0~15mm×2.0~15mm for example. In this case, the surface

area of the specific region accounted for by the respective coloration pads is set to be no more than 2.0mm^2 for example.

The analytical kit of the present invention is typically designed such that at least two of the plurality of coloration pads differ from each other with respect to coloration components for allowing measurement of a plurality of items.

A second aspect of the present invention provides a method for producing a test kit, which comprises a first step of forming a plurality of coloration pads by coating a carrier with a reagent liquid containing a coloration component using a non-contact dispenser and by thereafter drying the reagent liquid, and a second step of intimately attaching a penetration membrane so as to cover the plurality of coloration pads. The penetration membrane used in the second step allows liquid penetration mainly thicknesswise of the penetration membrane while restricting liquid penetration in the planar direction of the penetration membrane.

The penetration membrane in this aspect can be the same as that described for the first aspect above.

The non-contact dispenser used in the first step is of an inkjet type. The non-contact dispenser may also be one that employs a dispenser discharge system.

In the first step, the plurality of coloration pads are formed in a matrix arrangement for example. The

plurality of coloration pads may instead be formed so as to be linearly aligned.

In the first step, at least two of the plurality of coloration pads may differ from each other with respect to coloration components. Specifically, the present invention is applicable to the production of an analytical kit capable of analyzing a plurality of items.

In the first step, the plurality of coloration pads are formed within a specific region with a surface area of 2.0~15mm×2.0~15mm. In this case, the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0mm^2, for example.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an overall oblique view of the test kit pertaining to the first embodiment of the present invention;

Fig. 2 is a cross section along the II-II line in Fig. 1;

Fig. 3 is a cross section illustrating an analysis method that makes use of the test kit shown in Figs. 1 and 2;

Fig. 4 is a cross section illustrating an analysis method that makes use of the test kit shown in Figs. 1 and 2;

Fig. 5 is an overall oblique view of the test kit pertaining to the second embodiment of the present invention;

Fig. 6 is a cross section illustrating the action of the test kit shown in Fig. 5;

Fig. 7 is an overall oblique view of a conventional test kit;

Fig. 8 is a cross section along the VIII-VIII line in Fig. 7;

Fig. 9 is an overall oblique view of another example of a conventional test kit; and

Fig. 10 is a cross section along the X-X line in Fig. 9.

BEST MODE FOR CARRYING OUT THE INVENTION

Figs. 1 and 2 illustrate a test kit according to a first embodiment of the present invention. A test kit 1 is designed to analyze a plurality of items using a single sample liquid, and comprises a carrier 2, a plurality of coloration pads 3, and a penetration layer 4.

The carrier 2 is made of a material with low liquid penetrability, such as PET, PC, or a like resin material.

The plurality of coloration pads 3 are arranged in a matrix. In the drawings, there are a total of nine coloration pads 3 arranged in three rows and three columns, but the number of coloration pads 3 is a design matter, and is not limited to nine.

The coloration pads 3 each react with a specific substance in a sample liquid such as urine or blood, and change color depending on the amount of the specific component. The coloration pads 3 are formed in a circular shape with a diameter of about 1 mm using a non-contact dispenser, for example. The coloration pads 3 are circular in the drawings, but may instead be formed in a rectangular shape or the like. However, the surface area of the coloration pads 3 is preferably set to be no more than 2.0 mm^2.

The non-contact dispenser can be one that employs an inkjet system or a dispenser discharge system. With an inkjet system, for example, reagents each containing a desired coloration agent are deposited on the carrier 2, after which each deposit of the reagents is dried to form a respective coloration pad 3. With this method, the individual coloration pad 3 can be formed to have a desired size and shape by depositing a reagent liquid a plurality of times. For example, the coloration pad can formed into a circle having a diameter of about 1mm by controlling the droplet size of the reagent liquid.

The penetration layer 4 allows liquid penetration mainly in its thickness direction and restricts liquid penetration in its planar direction. The penetration layer is formed in a size of 2.0~15mm×2.0~15mm, for example. The penetration layer 4 may be provided by

intimately attaching a penetration membrane to the coloration pads 3 by hot-press bonding, for example.

As shown well in Fig. 2, the penetration membrane is one having numerous pores 40 extending in the thickness direction. In Fig. 2, however, the size of the pores is exaggerated, and the pores 40 do not necessarily have to extend linearly in the thickness direction. What is important is that they impart substantially thicknesswise liquid penetrability to the penetration membrane. The penetration membrane may comprise a glass filter, a honeycomb structure membrane, or a track etched membrane formed by track etching, for example. A typical example of a track etched membrane is "Cyclopore" available from Whatman.

Track etching is a process in which a polymer film made of a polycarbonate or polyester, for example, is bombarded with neutrons, and pores are then formed by chemical etching. With this process, the pore size and porosity can be controlled by varying the neutron bombardment time or the etching treatment time. With the present invention, the penetration membrane is one having a pore size of 0.1~12μm and a porosity of 4~20%, for example.

In analyzing a sample liquid with the use of the test kit 1, the penetration layer 4 of the test kit 1 is first spotted with a sample liquid S, as shown in Fig. 3. If the size of the penetration layer 4 is about 5×5mm,

the amount of the sample liquid S spotted to the test kit 1 will be 4~6μL (corresponds to droplets with a diameter of about 2~3mm), for example.

With the test kit 1, since the penetration layer 4 is formed of a penetration membrane having primarily thicknesswise liquid penetrability, the spotted sample liquid S moves mainly downward in the thickness direction through the pores 40. As a result, the sample liquid S is guided by the pores 40 to the coloration pads 3, and the sample liquid S is supplied to the coloration pads 3.

Then, as shown in Fig. 4, the coloration agents and the specific components in the sample liquid are allowed to react for a specific length of time, after which a plurality of items are analyzed by optically observing the extent of coloration in the coloration pads 3. More specifically, a light source 50 is used to irradiate the coloration pads 3 with light, the reflected light is received by a photosensor 51, and then the extend of coloration in the coloration pads 3, or the concentration of the specific components in the sample liquid, is calculated on the basis of the amount of light received.

According to the present embodiment, the sample liquid S penetrates thicknesswise through the penetration layer 4 due to the plurality of pores 40, and therefore does not spread out in the planar direction of the penetration layer 4. Accordingly, it is possible to suppress the formation of liquid junctions between

adjacent coloration pads 3, thereby restraining the coloration component from one coloration pad 3 from mixing into an adjacent coloration pad 3; i.e., ensuring less interference between adjacent coloration pads 3. This suppression of interference is achieved merely by forming the penetration layer 4 by applying a penetration membrane having characteristic penetrability in the thickness direction. Put another way, interference can be suppressed merely by employing a different penetration membrane from that used in the past, without entailing any additional producing steps. Therefore, the test kit 1 can be produced cost-advantageously because no costly apparatus is needed to suppress interference, and no special treatment is required.

Further, if interference can be suppressed, the adjacent coloration pads 3 can be placed closer together. This affords a smaller overall size of the test kit 1, and particularly when a sample liquid is to be analyzed, this affords a smaller surface area of the region to be spotted with the sample liquid, or region to be irradiated with light (optical irradiation area). As a result, the amount of sample liquid S that is required can be reduced, so when blood is used as the sample liquid S, for example, the user has to collect less blood. Moreover, if the optical irradiation area is made smaller, the light reflected from this area can be received all at once with a C-MOS sensor, a CCD sensor, or the like,

allowing the measurement device to be more compact. When the coloration pads 3 are formed by an inkjet process and in the form of a circle or rectangle having a diameter or size of about 1 mm, a plurality of coloration pads 3 for measuring a plurality of items can be put together in a small area in which only one item could be measured in the past, which means that the amount of carrier and coloration components (reagents) to be used can be reduced. This affords a reduction in material cost while also reducing the amount of waste.

In this embodiment, the sample liquid was analyzed on the basis of the reflected light produced by irradiation with light from the penetration layer side, but the design may instead be such that the carrier is formed from a transparent material, and the sample liquid is analyzed on the basis of the amount of transmitted light. Further, if the carrier is transparent, the design may be such that the optical irradiation is from the back side of the carrier, and the sample liquid is analyzed on the basis of the amount of reflected or transmitted light.

Next, a test kit according to a second embodiment of the present invention will be described through reference to Figs. 5 and 6. The analytical kit 1B shown in these figures is configured such that a penetration layer 4B is formed over an absorbent carrier 2B, and a plurality of

coloration pads 3B are arranged in a matrix on the penetration layer 4B.

The absorbent carrier 2B is porous, for example, and is formed so as to be liquid penetrable in at least the planar direction of the absorbent carrier 2B. Examples of absorbent carrier 2B include paper materials, foams, woven fabric materials, nonwoven fabric materials, knit materials, glass filters, and gelled materials.

The penetration layer 4B and the coloration pads 3B are formed by lamination, in that order, on the absorbent carrier 2B so as to cover approximately half of area of the absorbent carrier 2B. The penetration layer 4B is formed by bonding to the absorbent carrier 2B the same penetration membrane as that described in the first embodiment. The coloration pads 3B are formed over the penetration layer 4B by an inkjet process, for example.

With the test kit 1B, as shown well in Fig. 5, a sample liquid S spotted to the absorbent carrier 2B spreads out over the entire absorbent carrier 2B by capillary action. A portion of the sample liquid S held in contact with the penetration layer 4B is drawn up by the penetration layer 4B, which is combined with the absorbent carrier to provide a powerful capillary action for example, for supply to the coloration pads 3B. Thereafter, a plurality of items are optically checked in the same manner as in the first embodiment.

Since the test kit 1B comprises the penetration layer 4B which characteristically allows liquid to penetrate in its thickness direction, just as in the first embodiment, interference between adjacent coloration pads 3B can be suppressed while keeping the test kit 1B compact, all of which is achieved at low cost.